# California Health Benefits Review Program

Analysis of California Assembly Bill 1904 Pelvic Floor Physical Therapy Coverage

A Report to the 2019–2020 California State Legislature

May 5, 2020



# Key Findings Analysis of California Assembly Bill 1904 Pelvic Floor Physical Therapy Coverage

Summary to the 2019–2020 California State Legislature, May 5, 2020



# AT A GLANCE

The version of California Assembly Bill (AB) 1904 analyzed by CHBRP would require all stateregulated health insurance plans and policies to cover pelvic floor physical therapy, also referred to as pelvic floor muscle training (PFMT), for enrollees and beneficiaries after pregnancy.

- 1. CHBRP estimates that, in 2020, of the 21.7 million Californians enrolled in state-regulated health insurance, 21.7 million of them would have insurance subject to AB 1904.
- 2. **Benefit coverage**. CHBRP estimates that AB 1904 would increase statewide benefit coverage by 0.1% The bill's coverage would be unlikely to exceed the essential health benefits (EHBs).
- 3. **Utilization.** Due to 99.9% baseline coverage for pelvic floor physical therapy, CHBRP estimates there would be an increase of 100 enrollees utilizing pelvic floor muscle training after pregnancy.
- 4. **Expenditures**. CHBRP estimates a 0.0001% increase in expenditures as a result of increase in utilization.
- 5. Medical effectiveness. There is inconclusive evidence that PFMT is effective at treating urinary incontinence in women up to 12 months postpartum, and a preponderance of evidence that PFMT is effective at treating urinary incontinence in nonpostpartum women. There is limited evidence that PFMT is not effective at treating *fecal incontinence* in women, limited evidence that PFMT is effective at reducing some symptoms of *pelvic organ* prolapse, insufficient evidence to suggest that PFMT is effective/not effective at treating pelvic pain in postpartum women, and limited evidence that PFMT is effective at reducing pelvic pain in nonpostpartum women.
- 6. **Public health.** Because utilization per 1,000 covered enrollees is not expected to change, CHBRP estimates no measurable public health impact.

7. **Long-term impacts.** It appears unlikely that AB 1904 would have long-term cost or public health impacts due to existing coverage for PFMT.

# CONTEXT

Pelvic floor physical therapy, also referred to as pelvic floor muscle training (PFMT), refers to a set of modalities that are used to prevent and treat pelvic floor dysfunction (PFD). Symptoms of PFD include urinary incontinence, fecal incontinence, pelvic organ prolapse, and pelvic pain. Primary risk factors for PFD include childbirth, which increases with number of births, and aging (menopause).

# **BILL SUMMARY**

AB 1904 would require all state-regulated health insurance, including Medi-Cal managed care, to cover pelvic floor physical therapy after pregnancy. Figure A notes how many Californians have health insurance that would be subject to AB 1904, those with insurance coverage not subject to AB 1904, and Californians that are uninsured. The full text of AB 1904 can be found in Appendix A.

#### Figure A. Health Insurance in CA and AB 1904



*Source:* California Health Benefits Review Program, 2020. *Notes:* \*Medicare beneficiaries, enrollees in self-insured products, etc.



# **IMPACTS**

# Benefit Coverage, Utilization, and Cost

# **Benefit Coverage**

CHBRP estimates that 99.9% of enrollees with insurance that would be subject to AB 1904 already have coverage for pelvic floor physical therapy. The 0.1% of the population subject to AB 1904 who do not have benefit coverage for pelvic floor physical therapy are a segment of those enrolled in CDI-regulated grandfathered individual market policies.

Current coverage of pelvic floor physical therapy was determined by a survey of the largest (by enrollment) health insurers in California. Responses to this survey represent 62% of enrollees with health insurance subject to state benefit mandates.

## Utilization

At baseline, CHBRP estimates that 74,200 enrollees will utilize pelvic floor muscle training after pregnancy. CHBRP estimates utilization would increase by 100 enrollees following enactment of AB 1904.

## Expenditures

AB 1904 would result in a \$73,000 (0.0001%) increase in total net annual expenditures, premiums, or enrollee expenses for covered and/or noncovered benefits.

## Medi-Cal

Among publicly funded DMHC-regulated health plans, CHBRP estimates no impact on Medi-Cal Managed Care because all Medi-Cal managed care plans currenly provide coverage for PFPT. Because AB 1904 does not apply to Medi-Cal Fee-for-Service or Medi-Cal County Organized Health Systems, CHBRP estimates no impact on these market segments.

# CalPERS

CHBRP estimates no measurable impact projected on CalPERS plans because baseline coverage among enrollees in these plans is 99.9%.

# Number of Uninsured in California

CHBRP estimates no measurable impact on the number of people who are uninsured in California

Because the change in average premiums does not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 1904.

# **Medical Effectiveness**

CHBRP examined the medical effectiveness of pelvic floor physical therapy (referred to widely in the medical literature as "pelvic floor muscle training" or PFMT) as a treatment modality (encompassing all techniques) for symptoms of PFD, known as pelvic floor disorders. These disorders include incontinence (urinary and fecal), pelvic organ prolapse, and pelvic pain after pregnancy, as well as any harms associated with PFMT.

CHBRP found:

- There is *inconclusive evidence*<sup>1</sup> that PFMT is effective at treating urinary incontinence in postpartum women (0–12 months after delivery);
- There is a *preponderance of evidence*<sup>2</sup> that PFMT is effective at treating urinary incontinence in nonpostpartum women;
- There is *limited evidence*<sup>3</sup> that PFMT is not effective at treating fecal incontinence in women;
- There is *limited evidence* that PFMT is effective at treating pelvic organ prolapse in postpartum or nonpostpartum women;
- There is *insufficient evidence*<sup>4</sup> as to whether PFMT is effective at treating pelvic pain in postpartum women (0–12 months after delivery);

<sup>&</sup>lt;sup>1</sup> *Inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

<sup>&</sup>lt;sup>2</sup> *Preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

<sup>&</sup>lt;sup>3</sup> *Limited evidence* indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation. <sup>4</sup> *Insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.



- There is *limited evidence* that PFMT is effective at treating pelvic pain in nonpostpartum women, and;
- No trials reported harmful effects of PFMT.

# **Public Health**

Despite some evidence of effectiveness of PFMT, CHBRP concludes that the passage of AB 1904 would have no short-term public health impact due to 99.9% baseline coverage for PFMT. However, health outcomes may improve for the 100 enrollees who would newly utilize PFMT under AB 1904.

# **Long-Term Impacts**

CHBRP estimates no measurable long-term utilization, cost, or public health impacts due to 99.9% baseline coverage.

At the time of this CHBRP analysis, there is substantial uncertainty regarding the impact of the COVID-19 pandemic on premium rates and health plan enrollment, including how the pandemic will impact healthcare costs in 2021. Because the variance of potential outcomes is significant, CHBRP does not take these effects into account as any projections at this point would be speculative, subject to federal and state decisions and guidance currently being developed and released. In addition, insurers', providers', and consumers' responses are uncertain and rapidly evolving to the public health emergency and market dynamics.

# A Report to the California State Legislature

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May 5, 2020

California Health Benefits Review Program MC 3116; Berkeley, CA 94720-3116 www.chbrp.org

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# **REVISION HISTORY**

Date	Description of Revisions
May 5, 2020	This report has been updated to include a carrier survey response received after the initial report was published, which resulted in decrease of baseline utilization from 100% to 99.9%. The Benefit Coverage, Utilization, and Cost Impacts, Public Health, and Long- Term Impacts sections have been updated along with Tables 1, 6, and 7, and Appendix C.



The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications, are available at www.chbrp.org.

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Table 1. Ab 1904 impacts on benefit (	Baseline (2021)	Postmandate Year 1 (2021)	Increase/ Decrease	Change Postmandate
Benefit Coverage	(/			
Total enrollees with health insurance subject				
to state-level benefit mandates (a)	21,719,000	21,719,000	0	0.00%
Total enrollees with health insurance subject	· ·			
to AB 1904	21,719,000	21,719,000	0	0.00%
Percentage of enrollees with health insurance subject to AB 1904	100.0%	100.0%	0.0%	0.00%
Percentage of enrollees with health insurance fully compliant with AB 1904	99.9%	100.0%	0.1%	0.10%
Utilization and Cost				
Number of enrollees utilizing pelvic floor				
muscle training after pregnancy	74,200	74,300	100	0.13%
Counts of visits - pelvic floor muscle training	F00 <b>7</b> 00	F 40,000	<u> </u>	0.440/
after pregnancy Utilization per 1,000 covered enrollees - pelvic	539,700	540,300	600	0.11%
floor muscle training after pregnancy	24.87	24.88	0.01	0.04%
Average Cost/Visit - pelvic floor muscle				
training after pregnancy	\$111	\$111	\$0	0.00%
Expenditures				
Premium (expenditures) by Payer				
Private Employers for group insurance	\$54,037,059,000	\$54,037,059,000	\$0	0.00%
CalPERS HMO employer expenditures (b)	\$3,264,098,000	\$3,264,098,000	\$0	0.00%
Medi-Cal Managed Care Plan expenditures	\$29,218,820,000	\$29,218,820,000	\$0	0.00%
Enrollee Premiums (expenditures)			·	
Enrollees for individually purchased insurance	\$15,689,758,000	\$15,689,810,000	\$52,000	0.00%
Individually Purchased – Outside Exchange	\$4,412,875,000	\$4,412,927,000	\$52,000	0.00%
Individually Purchased – Covered	\$1,112,010,000	¢1,112,021,000	<i>\\</i> 02,000	0.0070
California	\$11,276,883,000	\$11,276,883,000	\$0	0.00%
Enrollees with group insurance, CalPERS				
HMOs, Covered California, and Medi-Cal	¢45 007 007 000	¢45 007 007 000	\$0	0.00%
Managed Care (b)	\$15,867,227,000	\$15,867,227,000	<del>۵</del> 0	0.00%
Enrollee out-of-pocket expenses				
For covered benefits (deductibles, copayments, etc.)	\$12,776,801,000	\$12,776,819,000	\$18,000	0.00%
Total Expenditures	\$130,853,763,000	\$130,853,833,000	\$70,000	0.00%

#### Table 1. AB 1904 Impacts on Benefit Coverage, Utilization, and Cost, 2021

Source: California Health Benefits Review Program, 2020.

*Notes:* (a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans. (b) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care

*Key*: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health

# **POLICY CONTEXT**

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)<sup>5</sup> conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 1904, Pelvic Floor Physical Therapy.

# **Bill-Specific Analysis of AB 1904, Pelvic Floor Physical Therapy**

### **Bill Language**

AB 1904 would require all plans regulated by the Department of Managed Health Care (DMHC), including Medi-Cal, and all policies regulated by the Department of Insurance (CDI) to "cover pelvic floor physical therapy after pregnancy." The full text of AB 1904 can be found in Appendix A.

#### **Relevant Populations**

If enacted, AB 1904 would affect the health insurance of approximately 21.7 million enrollees (54.5% of all Californians). This represents 100% of the 21.7 million Californians who will have health insurance that may be subject to state health benefit mandate laws — as regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI).

## **Pelvic Floor Physical Therapy Provider Certifications**

Pelvic floor physical therapy (used to treat symptoms of incontinence, pelvic organ prolapse, and sexual dysfunction) teaches correct contractions, muscle and body awareness, coordination and motor control, muscle strength and endurance, and relaxation (see *Background on Pelvic Floor Physical Therapy* section for more detail). AB 1904 does not define which providers would be authorized to provide pelvic floor physical therapy. Although licensed health providers (PT, MD, DO, NP, etc.) are not required to have particular training to offer these types of therapies, those without specific training do not regularly offer pelvic floor physical therapy; *pelvic floor physical therapy is usually provided by physical therapists with specialized pelvic floor physical therapy training*.<sup>6</sup>

The Academy of Pelvic Health Physical Therapy (APTA Pelvic Health) offers a Certificate of Achievement in Pelvic Health or Obstetric Physical Therapy (CAPP). Licensed physical therapists who complete required coursework through APTA Pelvic Health and a case reflection within a year of completing coursework are eligible to apply for these certifications. The American Board of Physical Therapy Services (ABPTS) offers a Specialist Certification in Women's Health, which requires licensed physical therapists to complete an exam, along with patient care requirements, to receive certification. The Herman & Wallace Pelvic Rehabilitation Institute also offers specialized training for physical therapists. See *Background on Pelvic Floor Physical Therapy* for more discussion of providers and training.

# **Interaction with Existing Requirements**

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

<sup>&</sup>lt;sup>5</sup> CHBRP's authorizing statute is available at www.chbrp.org/faqs.php.

<sup>&</sup>lt;sup>6</sup> Personal communication with content expert Lori Tuttle, Associate Professor, PT, PhD, San Diego State University, February 20, 2020.

# **California Policy Landscape**

#### California law and regulations

All DMHC-regulated plans and individual and small-group CDI policies are required to cover Basic Health Care Services (BHCS). DMHC considers pelvic floor physical therapy to be covered under BHCS when medically necessary.7

Small-group and individual polices regulated by CDI are also required to cover basic health care services.<sup>8</sup> As of the writing of this analysis, CDI has not indicated whether it considers pelvic floor physical therapy to be a service covered under BHCS.

#### Similar requirements in other states

CHBRP is not aware of similar requirements in other states' current law or pending legislation related to pelvic floor physical therapy.

#### **Federal Policy Landscape**

#### Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 1904 may interact with requirements of the ACA as presently exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).<sup>9,10</sup>

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law and regulations.

#### **Essential Health Benefits**

Nongrandfathered plans and policies sold in the individual and small-group markets are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.<sup>11,12</sup> CHBRP estimates that approximately 4 million Californians (10%) have insurance coverage subject to EHBs in 2021.13

Physical therapy is covered under the "rehabilitative and habilitative services and devices" category of EHBs in California's benchmark plan. The Department of Managed Health Care (DMHC) also considers

<sup>&</sup>lt;sup>7</sup> Personal communication with DMHC, February 24, 2020. For more information on BHCS, see Appendix B of CHBRP's resource Health Insurance Benefit Mandates in California State and Federal law, available on CHBRP's website: www.chbrp.org/other publications/index.php.

<sup>&</sup>lt;sup>8</sup> IC 1011.27.

<sup>&</sup>lt;sup>9</sup> The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other\_publications/index.php.

<sup>&</sup>lt;sup>10</sup> Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law. <sup>11</sup> CCIIO, Information on Essential Health Benefits (EHB) Benchmark Plans. Available at:

https://www.cms.gov/ccijo/resources/data-resources/ehb.html.

<sup>&</sup>lt;sup>12</sup> H&SC Section 1367.005; IC Section 10112.27.

<sup>&</sup>lt;sup>13</sup> CHBRP, Estimates of Sources of Health Insurance in California in 2021. Available at: www.chbrp.org/other publications/index.php.

pelvic floor physical therapy to be covered under Basic Health Care Services.<sup>14</sup> Therefore, the provisions of AB 1904 do not appear to exceed EHBs, and would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in QHPs in Covered California.

# **Analytic Approach and Key Assumptions**

Based on bill language parameters, CHBRP has assumed the following:

- Pelvic floor physical therapy is provided by physical therapists with supplemental, postgraduate training in pelvic floor physical therapy;<sup>15</sup>
- AB 1904 does not define "after pregnancy." While "after pregnancy" could mean during the postpartum period, it could also mean any time after pregnancy. CHBRP has assumed that AB 1904 would require coverage any time after pregnancy, regardless of the pregnancy's duration, outcome, or length of time since the pregnancy occurred;
- Pelvic floor physical therapy would be covered for any medical indication after pregnancy;
- "Pelvic floor physical therapy" is synonymous with "pelvic floor muscle training" (PFMT), a term that is used widely in the medical literature;<sup>16</sup>
- AB 1904 would not prohibit plans and policies from imposing utilization management measures on PFMT coverage, including requirement of "medical necessity";
- Coverage for any PFMT modalities would constitute compliance with the bill language; and
- Other treatments for pelvic floor dysfunction, including surgery and counseling on lifestyle changes, are not included in the bill.

At the time of this CHBRP analysis, there is substantial uncertainty regarding the impact of the COVID-19 pandemic on premium rates and health plan enrollment, including how the pandemic will impact healthcare costs in 2021. Because the variance of potential outcomes is significant, CHBRP does not take these effects into account as any projections at this point would be speculative, subject to federal and state decisions and guidance currently being developed and released. In addition, insurers', providers', and consumers' responses are uncertain and rapidly evolving to the public health emergency and market dynamics.

<sup>&</sup>lt;sup>14</sup> Personal communication with DMHC, February 24, 2020. For more information on BHCS, see Appendix B of CHBRP's resource *Health Insurance Benefit Mandates in California State and Federal law*, available on CHBRP's website: www.chbrp.org/other\_publications/index.php.

<sup>&</sup>lt;sup>15</sup> Personal communication with L Tuttle, PT, PhD, February 28, 2020.

<sup>&</sup>lt;sup>16</sup> Personal communication with L Tuttle, PT, PhD, February 28, 2020.

# **BACKGROUND ON PELVIC FLOOR PHYSICAL THERAPY**

AB 1904 would require coverage for pelvic floor physical therapy after pregnancy. CHBRP will follow evidence-based nomenclature, which calls the therapy "pelvic floor muscle training." This section provides contextual information for AB 1904 including:

- Definition of pelvic floor dysfunction (PFD, the condition for which pelvic floor muscle training is performed);
- Risk factors and prevalence rates for PFD; and
- Description of pelvic floor muscle training (PFMT) techniques.

Although PFD affects both women and men, AB 1904 specifies coverage "after pregnancy" thus, this analysis focuses only on women who have ever experienced pregnancy. CHBRP uses the most recent data available, with a focus on California data when possible.

# **Pelvic Floor Dysfunction**

The pelvic floor is comprised of a group of muscles that sit at the base of the abdomen, wrapping around the pelvis and forming the pelvic diaphragm (NIH, 2020). These muscles support the pelvic organs, help maintain optimal intraabdominal pressure, and relax and contract together as part of the urinary and bowel systems (Silviera and Keller, 2019).

Weakness or damage to one or more of the pelvic floor muscles, ligaments, and/or nerves can lead to generalized PFD, contributing to the onset of one or more symptoms known as "pelvic floor disorders" (Hallock and Handa, 2016; Raizada and Mittal, 2008) (Table 2).

Pelvic Floor Disorders	Associated Symptoms
Urinary Incontinence (a)	Involuntary loss of urine.
Stress Urinary Incontinence (a)	Urine leakage after coughing, sneezing, laughing, exercising, or lifting something heavy.
Urge Urinary Incontinence (a)	Having a sudden, intense urge to urinate, followed by urine leakage.
Overflow Urinary Incontinence (a)	Frequent or constant dribbling of urine due to a bladder that doesn't empty completely.
Mixed Urinary Incontinence (a)	Experiencing more than one type of urinary incontinence.
Pelvic Organ Prolapse (POP) (b) (c)	A condition in which pelvic organs collapse into the vagina or rectum. Severity is measured by the Pelvic Organ Prolapse Quantification system, with severity levels ranging from 0 to 4 (4 being the highest severity).
<i>Uterine Prolapse</i> (c)	A disorder in which the uterus drops down into the vagina. In severe cases, the uterus may protrude from the vagina.
Bladder Prolapse (Cystocele) (c)	The bladder drops, creating a bulge in the vagina. In severe cases, the bulge created by this drop may protrude outside the vagina.
Rectal Prolapse (Rectocele) (c)	The rectum drops down, creating a bulge in the vagina. In severe cases, the bulge can protrude outside the vagina.
Vaginal Vault Prolapse (c)	The top of the vagina drops down, and in severe cases, may protrude outside the vagina. Females who have received a hysterectomy are more likely to experience this type of prolapse than females who have not undergone this type of procedure.
Fecal Incontinence (d)	Involuntary loss of liquid or solid stool.
Pelvic Pain (c)	Can include any combination of muscle pain, vulvodynia, dyspareunia, taut bands, or trigger points. Pain sources may extend from nerve injuries, muscle weakness, and/or joint laxity from hormonal changes during pregnancy.

#### Table 2. Pelvic Floor Disorders and Associated Symptoms

Source: California Health Benefits Review Program, 2020.

Notes: (a) Mayo Clinic, 2020; (b) NIH, 2018; (c) Culligan, 2012; (d) Sinn, 2018; (e) Bo et al., 2017

# **Risk Factors for Pelvic Floor Dysfunction**

Childbirth and age are the primary risk factors for PFD (Handa et al., 2012; NIH, 2018; Wu et al., 2014). Other risk factors include chronic constipation, connective tissue disorders, hysterectomy, obesity, family history, smoking, diabetes, and participation in high-impact activities (Hartigan and Smith, 2018; NIH, 2018).

## Childbirth

Increased risk of PFD occurs with pregnancy, greater number of total births (vaginal or caesarean), greater number of vaginal births, forceps-assisted births, having more than one episiotomy or tear, and greater infant birth weight (Dietz and Simpson, 2007; Handa et al., 2012; NIH, 2018). Women who experience a pelvic floor disorder immediately postpartum may continue to experience symptoms until treatment is obtained (Gyhagen et al., 2013; MacArthur et al., 2016).

## Aging

The aging process (menopause) contributes to hormonal changes that can influence the pelvic floor and pelvic organs, possibly resulting in a decline in muscle strength due to normal aging (Biroli, 2016). Compounded with a history of childbirth, the aging process can contribute to the onset of PFD years after childbirth (Handa et al., 2012; Leijonhufvud et al., 2012). The peak hazard rates for developing fecal incontinence and stress urinary incontinence have been shown to occur within the first 5 years after childbirth, whereas pelvic organ prolapse may not occur until 20 years after childbirth (Blomquist et al., 2018).

# **Pelvic Floor Dysfunction Prevalence in the U.S.**

Estimating the prevalence of PFD is challenging due to the sensitive nature of the condition and the reliability of the data collection tools used (e.g., self-reported survey responses vs. physical examinations). Surveys using self-reported information may over- or underestimate true prevalence; and, although physical exams may accurately diagnose PFD, not all women with a pelvic floor disorder seek or receive specialty medical care, which likely results in an undercount (NIH, 2018).

The National Health and Nutrition Examination Survey (NHANES) uses both survey and physical exam methods, which improves data accuracy. The NHANES analysis by Wu et al. (2014) showed that about 21% of women (who were not currently pregnant) experienced at least one pelvic floor disorder, and about 34% of women with four or more births experienced a disorder (Table 3). Persistent urinary incontinence is fairly common immediately following childbirth, with 29.6% of women experiencing some form of urinary incontinence within the first 3 months postpartum (Gartland et al., 2016). Nygaard et al. (2017) estimated that, after one vaginal delivery, 25% to 50% of women will experience a mild pelvic organ prolapse within the first year postpartum, while 50% will experience urinary incontinence, and 17% will experience fecal incontinence within that same timeframe.

Women who experienced pelvic floor disorders during pregnancy are significantly more likely to experience the symptoms into and beyond the postpartum period (Gartland et al., 2012; Gartland et al., 2016). Table 3 shows the increasing prevalence of PFD as women age, with almost 40% of women aged 50 to 59 years experiencing at least one disorder (Wu et al., 2014).

Eight-five percent of women have been pregnant at least once prior to menopause (~age 45) (Martinez et al., 2018). Wu et al. (2009) applied pelvic floor disorder prevalence rates to the growing elderly population and estimate that 43.8 million women will have at least one pelvic floor disorder by 2050. Kirby et al. also predict a growing number of women seeking treatment for dysfunction, in part due to an increase in true prevalence and in part due to an increase in awareness of PFD and treatment options (Kirby et al., 2013).

Demographics	% of Females
Age	
Overall	25.0%
20-29	6.3%
30-39	13.6%
40-49	31.6%
50-59	38.5%
60-69 <sup>b</sup>	39.6%
Race/Ethnicity	
Hispanic, Mexican American	24.0%
Hispanic, other	20.0%
Non-Hispanic white	26.4%
Non-Hispanic black	20.0%
Other, including multi-racial	22.6%
Body Mass Index	
<25.0	17.8%
25.0 - 29.9	26.5%
>30.0	31.1%
Parity (# of births)	
0	11.5%
1	21.1%
2	23.8%
3	28.7%
≥4	33.6%

Table 3. Weighted Prevalence of Pelvic Floor Dysfunction by Key Demographic Characteristics in
the US, 2014 <sup>a</sup>

Source: California Health Benefits Review Program, 2020 (based on Wu et al., 2014).

*Notes*: (a) Data collected from interview and physical examination through the National Health and Nutrition Examination Survey (NHANES) (Wu et al., 2014).

(b) CHBRP predicts that this bill would have minimal impact on adults 65 years or older. According to Wu et al., 2014, more than 50% of women experience one or more pelvic floor disorders after 80 years of age.

# **Pelvic Floor Muscle Training (PFMT)**

PFMT is considered to be a conservative (i.e., nonsurgical), first-line treatment for some pelvic floor disorders related to PFD, including stress urinary incontinence, pelvic organ prolapse, and pelvic pain (Wallace et al., 2019). PFMT is defined as exercise therapy that improves pelvic floor muscle strength, endurance, power, relaxation, or a combination of these parameters (Wallace et al., 2019). The goal of therapy is to restore muscle imbalances, improve function, and reduce pain (Eickmeyer and Seslija, 2015).

Other conservative treatments that address pelvic floor disorder symptoms can include cognitive behavioral therapy (CBT), lifestyle modifications such as diet and exercise, fluid restriction, patient education, motivational interviewing, coping strategies, scheduled voiding regimes, bowel habit training, and practicing urgency suppression techniques (Bo et al., 2017). These services may be provided by practitioners from a variety of disciplines, including physical therapists, nurse practitioners, midwives,

medical doctors, and/or fitness instructors (Bo et al., 2017). Surgery is available for the more serious cases and may be used in place of or in conjunction with PFMT.

### **PFMT Providers**

The diagnosis of PFD and related disorders may be performed by obstetricians/gynecologists, urologists, urologists, and primary care physicians. The treatment of PFD using PFMT is primarily done by physiotherapists/physical therapists with specialty training in PFMT (Bo et al., 2017).<sup>17</sup> The number of physical therapists with pelvic floor specialty training in California is unknown, but is presumed to be limited.<sup>18</sup> Several websites identify these specialty physical therapists; however, the search capabilities are limited to local areas, and these sites only include members or certified practitioners from a specific training program (APTA, 2020).

Other providers involved in the treatment of PFD include the above physicians, who might recommend the nonphysical therapy conservative treatments (described above), or surgical intervention for PFD if PFMT fails or is not available.

#### **PFMT Techniques/Modalities**

PFMT includes multiple treatment techniques that work together and are individualized to the patient's needs. It often includes teaching correct contractions, muscle and body awareness, coordination and motor control, muscle strength and endurance, and relaxation (Dumoulin et al., 2018). Exercise therapy may also include education around the use of physical devices such as dilators or pessaries (Table 4). PFMT can also include manual muscle release by the physical therapist. The provider chooses treatment techniques appropriate for the condition(s) and patient needs, including those used during pregnancy for PFD prevention purposes (Bo and di Benedetto, 2010).

PFMT Techniques	
Biofeedback (a)	Biofeedback uses tools with external sensors to support technique and/or adherence to a PFMT program. These tools can include manometers, electromyography, ultrasound and/or MRI. Biofeedback equipment can be used during PFMT exercise to provide visual and/or auditory feedback to the patient regarding the strength and duration of their muscle contractions.
Electrical therapy (b)	Electrical therapy uses devices that deliver small, electrical currents directly to the target muscle for therapeutic purposes.
Magnetic stimulation (b)	Similar to electrical therapy but uses pulsing magnetic fields instead to produce muscle contraction and support PFMT.
Manual therapy (b)	Manual therapy is performed by a trained clinician, and can include massage, manipulation, or mobilization.
Mechanical devices (b)	Intravaginal or intra-anal devices used with PFMT exercises to support or strengthen pelvic floor muscles. Devices used for this purpose include weighted cones, dilators, and pessaries.

Source: California Health Benefits Review Program, 2020.

*Notes:* (a) Bo and di Benedetto, 2010

(b) Bo et al., 2017

*Key:* PFMT = pelvic floor muscle training

<sup>&</sup>lt;sup>17</sup> Personal communication with L Tuttle, PT, PhD, February 28, 2020.

<sup>&</sup>lt;sup>18</sup> Personal communication with L Tuttle, PT, PhD, February 28, 2020.

## **PFMT Treatment Pattern**

In most cases, PFMT can start once the individual is cleared for activity after childbirth, usually at 4 to 6 weeks for a vaginal birth, and 10 to 12 weeks for a cesarean.<sup>19</sup> Most pelvic physical therapists recommend weekly, 1-hour long sessions for 4 to 8 weeks, supplemented with a home exercise program between sessions (Wallace et al., 2019). If symptoms are more severe and/or complex, patients may need several additional months of treatment (Wallace et al., 2019).

# Disparities<sup>20</sup> and Social Determinants of Health<sup>21</sup> in Pelvic Floor Disorders

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDoH) as it relates to PFD. Disparities are differences between groups that are modifiable.

Disparities exist in prevalence of pelvic floor disorders. For example, one study demonstrated an increasing prevalence of pelvic floor disorders as cohorts aged (Table 5) with about 50% of women over age 80 years experiencing at least one disorder (Hartigan and Smith, 2018). Other studies presented evidence of racial/ethnic disparities in stress urinary incontinence and urge urinary incontinence. Asian-American women appear to have the lowest risk of urinary incontinence overall as compared with white and Hispanic women (Hartigan and Smith, 2018). Several studies showed that black women had highest rates of urge urinary incontinence while white women had three times the risk of stress urinary incontinence as black women and two times the risk of Asian American women (Hartigan and Smith, 2018; Sears et al., 2009). Hartigan and Smith note that this finding is unexpected due to the fact that black women have higher rates of other PFD risk factors such as smoking, obesity, diabetes, and hysterectomy (Hartigan and Smith, 2018). Finally, Hispanic women appear to have significantly elevated risk of pelvic organ prolapse as compared with white women (odds ratio [OR]=6.29, 95% CI: 4.20 to 9.41) (Hartigan and Smith, 2018).

## **Knowledge and Treatment Seeking**

Most women do not seek medical treatment despite high rates of pelvic floor disorders, although this pattern is more frequent among women of color than white women (Hartigan and Smith, 2018).

Reasons for not seeking treatment include:

- Embarrassment;
- Urinary incontinence assumed to be a normal part of postpartum status or aging; and
- Poor understanding of pelvic floor dysfunction/disorders and treatment options.

According to Mandimika et al. women of color were significantly less likely than white women to know that childbirth was a cause of urinary incontinence and that exercises can help control leakage (OR=3.49, CI: 1.74 to 7.01; and OR=2.33, 95% CI: 1.17 to 4.64, respectively). Women of color were also less likely than white women to know that pelvic organ prolapse can occur at any age, and to know that treatment options are available, including exercises that can be done to prevent progression (Mandimika et al., 2015).

There is conflicting evidence in identifying potential socioeconomic barriers for accessing PFMT. In the *Study of Women's Health Across the Nation*, Waetjen et al. (2015) reported no racial/ethnic,

<sup>&</sup>lt;sup>19</sup> Personal communication with L Tuttle, PT, PhD, February 28, 2020.

<sup>&</sup>lt;sup>20</sup> Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population. (Wyatt et al., 2016).

<sup>&</sup>lt;sup>21</sup> CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from: (CDC, 2014; Healthy People 2020, 2019)). See CHBRP's SDoH white paper for further information: <a href="http://chbrp.com/analysis">http://chbrp.com/analysis</a> methodology/public health impact analysis.php.

socioeconomic or educational differences in urinary incontinence treatment-seeking behavior among the 1,550 women (68%) who sought treatment for urinary incontinence. Berger et al. (2011) also found no racial disparities between black and white women from Michigan. These studies stand in contrast to another study finding a significant difference in treatment-seeking by white women with urinary incontinence as compared with Latina, black, and Asian women with urinary incontinence (70%, 16%, 6%, 5%, respectively) (Hartigan and Smith, 2018).

# **Societal Impact of Pelvic Floor Dysfunction**

The presence of PFD in the United States creates a societal impact. In dollar terms, the societal impact can be indirect (lost wages, etc.), as well as direct (medical care, etc.). Please note, the societal impact discussed here is relevant to a broader population than AB 1904 would impact.

Women with disorders stemming from PFD suffer physical and emotional distress and the economic effect of these disorders on the health care system is substantial (NIH, 2018). For 2005 and 2006, the estimated cost of ambulatory care for pelvic floor disorders in the United States was \$412 million (\$557.8 million adjusted to 2020 dollars) (Sung et al., 2010). The total economic burden of one of the pelvic floor disorders, urgency urinary incontinence, was \$66 billion in 2007 (\$83.7 billion adjusted to 2020 dollars) (Milsom et al., 2014). The estimated lifetime risk of surgery for either stress urinary incontinence or pelvic organ prolapse is 20% by age 80 years (Wu et al., 2014).

According to the National Institutes of Health (NIH) compendium of disease-specific costs, pelvic organ prolapse surgery (an alternative treatment to PFMT for dysfunction) had a direct cost of \$1.01 billion in 1997 (\$1.65 billion adjusted to 2020 dollars), similar to the costs associated with treating breast cancer or managing infertility (reviewed by Hu et al., 2005). Due to increasing life span, the number of women who undergo pelvic organ prolapse surgery is estimated to increase by 47% from 2010 to 2050 (Whiteside and Muffly, 2013; Wu et al., 2011) and costs are anticipated to continue to rise as the baby boomer generation ages and demand continues to increase (Wu et al., 2009).

# **MEDICAL EFFECTIVENESS**

As discussed in the *Policy Context* section, AB 1904 would require coverage for pelvic floor physical therapy after pregnancy. CHBRP will be using the term "pelvic floor muscle training" (PFMT) as it used more widely in the medical literature as the term for pelvic floor physical therapy. PFMT may include a variety of approaches including biofeedback, manual therapy, electrical therapy, magnetic stimulation, mechanical devices, and relaxation exercises (Table 4). Additional information on these treatment approaches, as well as pelvic floor disorders, prevalence and risk factors, is included in the *Background on Pelvic Floor Physical Therapy* section. The medical effectiveness review summarizes findings from evidence<sup>22</sup> on the effectiveness of PFMT as a treatment modality (encompassing all techniques) for pelvic floor disorders, including incontinence (urinary and fecal), pelvic organ prolapse, and pelvic pain after pregnancy, as well as any harms associated with PFMT. As AB 1904 is assumed to cover PFMT for women at any point in their lives following pregnancy, as described in the *Policy Context* section, evidence is reviewed for women both in the immediate postpartum period (0–12 months) and at any point in their lives.

# **Research Approach and Methods**

Studies of PFMT were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete, the Cumulative Index of Nursing and Allied Health Literature, and PsycINFO. Websites maintained by the following organizations that produce and/or index metaanalyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network. The search was limited to abstracts of studies published in English. CHBRP primarily relied on five Cochrane systematic reviews (Cheong et al., 2014; Dumoulin et al., 2018; Hagen and Stark, 2011; Norton and Cody, 2012; Woodley et al., 2017) for evidence on the effectiveness of PFMT. For more recent studies, the search was limited to studies published since the completion of these Cochrane reviews. Additional studies were identified by reviewing reference lists of relevant papers.

Of the 459 articles found in the literature review, 50 were reviewed for potential inclusion in this report on AB 1904, and a total of three studies (in addition to the five Cochrane reviews mentioned above) were included in the medical effectiveness review for this report. The other articles were eliminated because they were conducted exclusively in prenatal women, focused on PFMT for prevention of pelvic floor dysfunction (PFD), assessed prenatal PFMT on postpartum outcomes, or the PFMT regimens were not overseen by a physiotherapist or physical therapist. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.<sup>23</sup> Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

<sup>23</sup> Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP's use of grey literature, visit <a href="http://chbrp.com/analysis">http://chbrp.com/analysis</a> methodology/medical effectiveness analysis.php.

<sup>&</sup>lt;sup>22</sup> Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence on page 11 of the *Medical Effectiveness Analysis and Research Approach* document (posted at <u>http://chbrp.com/analysis methodology/medical effectiveness analysis.php</u>), in the absence of fully applicable to the analysis peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

# **Key Questions**

- 1. Is pelvic floor muscle training (PFMT) an effective treatment (as a group of modalities) for pelvic floor dysfunction (PFD), including urinary and fecal incontinence or urgency, pelvic organ prolapse, or pelvic pain?
- 2. Are there harms associated with PFMT?

# **Methodological Considerations**

Existing research on PFMT is primarily conducted in three populations:

- Pregnant women;
- Postpartum women (defined as women with symptoms up to 12 months after delivery); and
- Nonpostpartum women (all women regardless of prior pregnancy status).

In alignment with the language in AB 1904 mandating coverage for PFMT "after pregnancy," this medical effectiveness review excludes currently pregnant women, but includes women both in the immediate postpartum period (0–12 months) and at any point in their lives. Because 85% of US women have had at least one pregnancy during childbearing years, CHBRP assumes that the findings from studies that do not specify pregnancy experience also are applicable to the AB 1904 "after pregnancy" (ever been pregnant) population.

#### **Postpartum Women**

This medical effectiveness review relied on a Cochrane systematic review by Woodley et al. (2017) for evidence of the effectiveness of PFMT for the prevention or treatment of PFD specifically in postpartum women, defined by the review as "women immediately following delivery or women with persistent urinary or fecal incontinence symptoms up to three months after their most recent delivery." This review included 38 trials assessing PFMT in both pregnant and postpartum women; CHBRP reports results from 15 trials included in the review that were conducted in postpartum women for either treatment or mixed prevention and treatment ("mixed" meaning that some women had incontinence symptoms when randomized but others did not).

#### **Adult Women**

As previously discussed, this bill would require coverage for PFMT "after pregnancy." As "after pregnancy" was not further defined in the bill language, CHBRP assumed that the bill would apply to all women at any point in their lives after any pregnancy. As discussed in the *Background on Pelvic Floor Physical Therapy* section, the vast majority of women after age 45 years have had at least one pregnancy; as such, the medical effectiveness review made the assumption that evidence on the use of PFMT by any nonpregnant women is applicable to PFMT use by women after pregnancy.

This review relied on three Cochrane reviews for evidence on the effectiveness of PFMT in a general, female, adult (aged 18 years and older) population. The Dumoulin et al. (2018) review assessed the effectiveness of PFMT for the treatment of urinary incontinence (31 trials; 1,817 women). Average age of the women in the included trials was 57 years (range: 19–76 years). The Hagen and Stark (2011) review assessed the effectiveness of conservative management, including PFMT, on pelvic organ prolapse. Of the six trials included in the review, CHBRP reports results from four trials that compared PFMT to a control group (n=857); the average age of women included in these trials was 57 years (range: 48–67 years). Finally, the review by Cheong et al. (2014) provided evidence on the effectiveness of nonsurgical

interventions, including PFMT, on chronic pelvic pain. Of the 13 trials included in the review, CHBRP reports results from the single trial (n=48; age range: 18–64 years) comparing PFMT to a control arm.

## **Outcomes Assessed**

Studies of PFMT have primarily examined the effect on urinary incontinence and urgency, fecal incontinence, pelvic organ prolapse, and pelvic pain (such as dyspareunia and vulvodynia). Adverse effects of PFMT include pain and discomfort.

# **Study Findings**

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of PFMT to treat postpartum pelvic floor dysfunction addressed by AB 1904. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the strength of evidence about the effect of a particular test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms is included in the box below, and more information is included in Appendix B.

The following terms are used to characterize the body of evidence regarding an outcome:

*Clear and convincing* evidence indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

*Preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

*Limited evidence* indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

*Inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

*Insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

More information is available in Appendix B.

## **Effectiveness of Pelvic Floor Muscle Training**

#### Urinary incontinence

Woodley et al.'s (2017) Cochrane review included three randomized controlled trials (RCTs) (n=696) assessing the effectiveness of PFMT for the treatment of urinary incontinence in postpartum women who were incontinent when randomized during their pregnancy. The authors concluded that it is unclear whether PFMT reduced urinary incontinence at more than 6 to 12 months postpartum (relative risk [RR]=0.55, 95% CI: 0.29 to 1.07). The authors also noted that the evidence was very low quality due to timing of outcome reporting, crossover of PFMT in the control arms, attrition, and differential loss to

follow-up. This review also pooled three RCTs (n=826) assessing PFMT in a population of both asymptomatic and symptomatic women, meaning that some of the women were incontinent when randomized or others were continent. After more than 6 to 12 months' postpartum, those who were randomized to PFMT were 12% less likely to experience urinary incontinence than those randomized to the control arm (RR=0.88, 95% CI: 0.71 to 1.09). The authors concluded that it's unclear whether PFMT decreases urinary incontinence in a mixed population, citing very low–quality evidence due to the risk profile of women recruited and risk of bias of the included studies (e.g., lack of blinding, incomplete outcome data).

In the Dumoulin et al. (2018) Cochrane review, six studies randomized women with urinary incontinence to PFMT or a control arm and reported changes in incontinence symptoms. In four trials of women with stress urinary incontinence (n=165; mean age, 66 years), those assigned to PFMT were eight times more likely to report absence of incontinence symptoms after treatment ended versus the control group (RR=8.38, 95% CI: 3.68 to 19.07). In three trials (n=290; mean age, 73 years) including women with all types of urinary incontinence, women assigned to PFMT were five times more likely to report absence of symptoms after treatment ended versus the control group (RR=5.34, 95% CI: 2.78 to 10.26). Women with stress urinary incontinence or any type of urinary incontinence who were treated with PFMT were also more likely to report improvement in incontinence symptoms at the conclusion of treatment.

**Summary of findings regarding pelvic floor muscle training for urinary incontinence and urgency:** There is inconclusive evidence from one systematic review that PFMT performed in postpartum women (immediately following delivery or up to 12 months postpartum) is effective in reducing urinary incontinence. There is a preponderance of evidence from one systematic review reporting moderate-tohigh quality evidence that PFMT performed in nonpostpartum adult women is effective in reducing urinary incontinence. CHBRP notes that the average age of women in these studies is older than women whose coverage would be affected by AB 1904; however, there is no clear reason that PFMT would have a different impact on younger women.

# Figure 1. Pelvic Floor Muscle Training for Urinary Incontinence in Postpartum Women (0–12 Months After Delivery)

NOT EFFECTIVE					EFFECTIVE
Clear and Convincing	Preponderance	Limited	Limited	Preponderance	Clear and Convincing

#### Figure 2. Pelvic Floor Muscle Training for Urinary Incontinence in Nonpostpartum Women

<b>FEFFECTIVE</b>						EFFECT
					Λ	
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	PREPONDERANCE	Clear and Convincing

## Fecal incontinence

Woodley et al.'s (2017) Cochrane review included two trials (n=620) assessing the effectiveness of PFMT for the treatment of fecal incontinence in postpartum, continent women. The authors concluded that is unclear whether PFMT reduced fecal incontinence at more than 6 to 12 months postpartum (RR=0.68, 95% CI: 0.24 to 1.94). The authors also noted that the evidence was very low quality due to crossover of PFMT between the intervention and control arms and risk of study bias (e.g., lack of blinding, incomplete outcome data). Two trials (n=107) included in this review did not demonstrate a reduction in fecal incontinence between the PFMT and control arms in a population including both asymptomatic and symptomatic women.

Norton et al.'s (2012) Cochrane review included one trial (n=38; mean age, 60 years) randomizing women to PFMT plus surgery or surgery alone, and found no significant difference (mean difference=1.59, 95% CI: 0.31 to 3.49). Additionally, the Cochrane review concluded that sacral nerve stimulation provided stronger results for reducing the number of incontinence episodes after 12 months than PFMT (1 trial; n=120) (mean difference=6.30, 95% CI: 2.26 to 10.34). There is low-quality evidence that PFMT may be helpful for women with anal sphincter injuries.

**Summary of findings regarding pelvic floor muscle training for fecal incontinence:** There is limited evidence from one systematic review including four trials that PFMT is not effective in reducing fecal incontinence among postpartum women. There is limited evidence from one systematic review including two trials that that PFMT is not effective at reducing fecal incontinence among nonpostpartum, adult women.

# Figure 3. Pelvic Floor Muscle Training for Fecal Incontinence in Postpartum or Nonpostpartum Women



# Pelvic organ prolapse

The Woodley et al. (2017) review included two trials reporting changes in symptoms of pelvic organ prolapse among postpartum women randomized to PFMT compared to the control group. The first trial (n=175) surveyed women and found that at 6 months postpartum, women who underwent PFMT reported fewer symptoms of interior bulging (mean difference=0.37, 95% CI: 0.17 to 0.78) but similar symptoms of exterior bulging (mean difference=0.84, 95% CI: 0.27 to 2.66) and similar prolapse stage based on clinical assessment (mean difference=0.88, 95% CI: 0.46 to 1.70). The second trial (n=282) also reported similar pelvic floor symptoms (based on the Female Pelvic Floor Questionnaire [FPFQ]) among women randomized to PFMT or control (mean difference=3.90, 95% CI: -0.06 to 7.86).

One multisite, randomized controlled trial (POPPY study, n=447), assessed outcomes for participants, regardless of parity, receiving 16 weeks individualized pelvic floor muscle training sessions with home exercises, versus a prolapse lifestyle leaflet. Participants in the treatment group reported fewer symptoms at 6 months (adjusted difference=2.84, 95% CI: 2.05-3.63, p<0.0001). There was no significant difference between groups on improvement of prolapse stage based on clinical assessment (RR=1.39, 95% CI: 0.94 to 2.06, p=0.10) (Hagen et al., 2014).

**Summary of findings regarding pelvic floor muscle training for pelvic organ prolapse:** There is limited evidence from one systematic review including two trials that PFMT is effective at improving symptoms of pelvic organ prolapse among postpartum women. There is limited evidence from a single trial conducted in nonpostpartum women that PFMT is effective at improving symptoms of pelvic organ prolapse.

Figure 4. Pelvic Floor Muscle Training for Pelvic Organ Prolapse in Postpartum or Nonpostpartum Women

EFFECTIVE						EFFEC
				٨		
Clear and Convincing	Preponderance	Limited	Inconclusive	LIMITED	Preponderance	Clear and Convincing

## Pelvic pain

CHBRP did not identify any reviews or studies assessing the impact of PFMT on chronic pelvic pain among postpartum women.

The Cheong et al. (2014) Cochrane review assessed the effectiveness of nonsurgical interventions for the management of chronic pelvic pain and included one study (n=50; age range: 18–64 years) which randomized women with chronic pelvic pain to either PFMT or standard care (counselling). Physical treatment (distention of painful pelvic structures) resulted in significant reductions in pelvic pain scores and pain during intercourse compared with counseling.

One trial randomized postpartum women with pelvic pain to receive either PFMT and stabilizing exercises targeting abdominal muscles led by the physical therapist (n=20) or the stabilizing exercises alone (n=20). The PFMT protocol was performed over three weekly sessions for 12 weeks and included rhythmic and sustained contractions. Both groups reported decreases in pain and functional disability over the 12-week period, but women randomized to PFMT reported a significant decrease (p=0.001) in pain and functional disability compared to women receiving stabilizing exercises alone (EIDeeb et al., 2019).

Another trial randomized 42 women aged 40 to 60 years experiencing painful intercourse to either PFMT (n=21) or a heat application to the lower back for muscle relaxation (n=21). Women randomized to PFMT reported significant improvements in pain and sexual function (p<0.001) (Schvartzman et al., 2019).

**Summary of findings regarding pelvic floor muscle training for pelvic pain:** There is insufficient evidence regarding the effectiveness of PFMT in decreasing pelvic pain in postpartum women. There is limited evidence from one systematic review including one small trial and two additional small trials that PFMT is effective at decreasing pelvic pain in nonpostpartum women.

#### Figure 5. Pelvic Floor Muscle Training for Pelvic Pain in Postpartum Women (0–12 Months)

NOT EFFECTIVE		INSU	FFICIENT EVID	ENCE		EFFECTIVE
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

#### Figure 6. Pelvic Floor Muscle Training for Pelvic Pain in Nonpostpartum Women

EFFECTIVE						EFFECTI				
Clean and						Clean and				
Clear and Convincing	Preponderance	Limited	Inconclusive	LIMITED	Preponderance	Clear and Convincing				

## Harms Associated with Pelvic Floor Muscle Training

The Woodley et al. (2017) Cochrane review did not identify any trials reporting harmful effects of PFMT. Two trials included in the Dumoulin et al. (2018) review reported adverse events occurring among women randomized to PFMT. Harms include worsening incontinence symptoms upon starting treatment which ultimately resolved as treatment progressed (n=1), pain (n=1), and some discomfort during the PFMT exercises (n=3).

# **Summary of Findings**

Table 5 summarizes the evidence of the effectiveness of PFMT to treat incontinence, pelvic organ prolapse, and pelvic pain in women both in the immediate postpartum period (0–12 months) and at any point in their lives. The strongest evidence supports the use of PFMT for treating urinary incontinence in adult women, in studies that include women regardless of prior pregnancy status. There is limited evidence that PFMT is effective at reducing some symptoms of pelvic organ prolapse among all adult women and postpartum women, and limited evidence that it is effective at reducing symptoms of pelvic pain. There is also limited evidence that PFMT is not effective at treating fecal incontinence. No studies were identified addressing the effectiveness of PFMT in reducing pelvic pain among postpartum women.

Pelvic Floor Disorders	Postpartum Women (0-12 months)	Nonpostpartum Women
Urinary Incontinence	Inconclusive evidence that PFMT is effective in women up to 12 months postpartum	Preponderance of evidence that PFMT is effective
Fecal Incontinence	Limited evidence that PFMT is not effective in women up to 12 months postpartum	Limited evidence that PFMT is not effective
Pelvic Organ Prolapse	Limited evidence that PFMT is effective at reducing some symptoms of prolapse	Limited evidence that PFMT is effective at reducing some symptoms of prolapse
Pelvic Pain	Insufficient evidence	Limited evidence that PFMT is effective at reducing pelvic pain

Table 5. Summary of Evidence of Medical Effectiveness of Pelvic Floor Muscle Training

Source: California Health Benefits Review Program, 2020.

Key: PFMT = pelvic floor muscle training

# **BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS**

As discussed in the *Policy Context* section, AB 1904 would require all plans regulated by the Department of Managed Health Care (DMHC), including Medi-Cal, and all policies regulated by the Department of Insurance (CDI) to cover pelvic floor physical therapy after pregnancy.

This section reports the potential incremental impacts of AB 1904 on estimated baseline benefit coverage, utilization, and overall cost.

Current benefit coverage was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 62% of enrollees with health insurance subject to state benefit mandates. It is possible some enrollees in a smaller plan or policy may not have the same coverage.

# **Baseline and Postmandate Benefit Coverage**

Currently, 99.9% of enrollees with health insurance that would be subject to AB 1904 have coverage for pelvic floor physical therapy after pregnancy. The 0.1% of the population subject to AB 1904 who do not have benefit coverage for pelvic floor physical therapy are a segment of those enrolled in CDI-regulated grandfathered individual market policies.

Postmandate, CHBRP projects that 100% of enrollees with health insurance subject to AB 1904 would have coverage for pelvic floor physical therapy after pregnancy. This represents a 0.1% increase.

# **Baseline and Postmandate Utilization**

At baseline, approximately 74,200 enrollees use pelvic floor muscle training "after pregnancy" (which includes any woman ever pregnant). Baseline count of visits for pelvic floor muscle training after pregnancy is 539,700 visits. Appendix C details the sources and methods used to establish baseline estimates.

Postmandate, 0.1% of enrollees would gain compliant coverage with AB 1904, which would increase utilization by 600 visits, to 540,300. Utilization per 1,000 covered enrollees would remain flat at 24.88.

# **Baseline and Postmandate Per-Unit Cost**

Assuming that physical therapists are the likely providers of this service, baseline average cost for pelvic floor muscle training is \$111 (see Table 1). Postmandate, there would be no measurable difference in per-unit cost of pelvic floor physical training. Appendix C details the sources and methods used to establish the per-unit cost.

# **Baseline and Postmandate Expenditures**

Table 6 and Table 7 present baseline and postmandate expenditures by market segment for DMHCregulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

AB 1904 would increase total net annual expenditures for enrollees with DMHC-regulated plans and CDIregulated policies by 0.0001%, or \$73,000.

## Premiums

Also, there would be a 0.0003% change in premiums as a result of AB 1904, an increase of \$54,000

Among publicly funded DMHC-regulated health plans, there would be no measurable changes in premiums as a result of AB 1904 for DMHC-regulated enrollees associated with Medi-Cal Managed Care and with CalPERS because enrollees in these plans have 100% baseline coverage.

### **Enrollee Expenses**

AB 1904–related changes in enrollee expenses for covered benefits (deductibles, copays, etc.) and enrollee expenses for noncovered benefits would not vary by market segment.

CHBRP projects an increase of 0.0001% or \$19,000 in copayments or coinsurance rates but no increase in utilization of pelvic floor physical training after pregnancy per thousand enrollees. Therefore, there is no projected measurable impact on enrollee cost sharing.

It is possible that some enrollees incurred expenses related to pelvic floor physical training after pregnancy for which coverage was denied (e.g., deemed not medically necessary), but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact.

#### Out-of-pocket spending for covered and noncovered expenses

While it is possible some enrollees without coverage at baseline pay for noncovered PFPT out-of-pocket at baseline, CHBRP is unable to estimate such utilization. Therefore, CHBRP estimates no measurable noncovered expenses at baseline; consequently, CHBRP estimates no measurable impact on out-of-pocket spending for covered and noncovered expenses associated with AB 1904–relevant treatments.

#### Potential Cost Offsets or Savings in the First 12 Months After Enactment

CHBRP does not project any cost offsets or savings in health care that would result because of the enactment of provisions in AB 1904 due to 99.9% baseline coverage.

#### **Postmandate Administrative Expenses and Other Expenses**

CHBRP estimates that the increase in administrative cost of DMHC-regulated plans and/or CDI-regulated policies will remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative cost. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

## **Other Considerations for Policymakers**

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

#### Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 6 and Table 7), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 1904.

## **Changes in Public Program Enrollment**

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 1904.

## How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

CHBRP estimates that AB 1904 would not have a measurable impact in shifts of benefit coverage to other payers.

		DMHC-Regulated CDI-Regulated										
	Commerci	al Plans (by M				icly Funded Pl MCMC	lans			al Plans (by		
	Large Group	Small Group	Individual		CalPERS HMOs (b)	(Under 65) (c)	МСМС (65+) (с)		Large Group	Small Group	Individual	TOTAL
Enrollee Counts												
Total enrollees in plans/policies subject to state mandates (d)	7,797,000	2,127,000	1,938,000		522,000	7,481,000	875,000		645.000	174.000	160.000	21,719,000
Total enrollees in plans/policies subject to AB 1904	7,797,000	2,127,000	1,938,000		522,000	7,481,000	875,000		645,000	174,000	160,000	21,719,000
Premium Costs												
Average portion of premium paid by employer	\$421.33	\$387.36	\$0.00		\$521.09	\$262.75	\$536.28		\$493.36	\$435.79	\$0.00	\$86,519,976,000
Average portion of premium paid by enrollee	\$109.79	\$140.13	\$632.59		\$97.10	\$0.00	\$0.00		\$137.09	\$167.01	\$509.49	\$31,556,986,000
Total Premium	\$531.12	\$527.49	\$632.59		\$618.19	\$262.75	\$536.28		\$630.44	\$602.80	\$509.49	\$118,076,962,000
Enrollee Expenses	·	·				·				<u>.</u>		· <i>, , ,</i>
Enrollee expenses for covered benefits (deductibles, copays, etc.)	\$41.92	\$115.98	\$170.63		\$51.02	\$0.00	\$0.00		\$123.80	\$161.70	\$161.76	\$12,776,801,000
Enrollee expenses for noncovered benefits (e)	\$0.00	\$0.00	\$0.00		\$0.00	\$0.00	\$0.00		\$0.00	\$0.00	\$0.00	\$0
Total Expenditures	\$573.05	\$643.47	\$803.22		\$669.20	\$262.75	\$536.28		\$754.24	\$764.50	\$671.25	\$130,853,763,000

#### Table 6. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2021

Source: California Health Benefits Review Program, 2020.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Approximately 57.36% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

#### Table 7. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2021

Commercial Plans (by Market) (a)       Publicly Funded Plans       Commercial Plans (by Market) (a)         Large       Small       Individual       CalPERS       MCMC       Large       Small       Individual       TOTAL         Enrollee Counts       Image	rcial Plans (by Market) (a)					hotelur	Ro	DMHC			
Large Group       Small Individual Group       Individual       CalPERS HMOs (b)       MCMC (Under 65) (c)       MCMC (65+) (c)       Large Group       Small Group       Individual       TOTAL         Enrollee Counts       Image Counts	Small	Commercia		DMHC-Regulated							
Large     Small     Individual     CalPERS     MCMC     Large     Small     Individual     TOTAL       Group     Group     Individual     HMOs (b)     (c)     (65+) (c)     Group     Group     Individual     TOTAL	Small Individual TOTAL	Commercial Plans (by Market) (a)								Commerci	
	Group Individual TOTAL	•			(Under 65)			Individual		•	
Total enrollees in plans/policies											
											Total enrollees in plans/policies
	0 174,000 160,000 21,719,000	645,000		875,000	7,481,000	522,000		1,938,000	2,127,000	7,797,000	
		0.45.000		075 000	7 404 000	500.000		4 000 000	0 407 000		
	0 174,000 160,000 21,719,000	645,000	-	875,000	7,481,000	522,000		1,938,000	2,127,000	7,797,000	
Premium Costs			_				_				
Average portion of premium		<b>*</b> ••••••		<b>*</b> ••••••	<b>*•</b> • • • • •	<b>*</b> ~ ~~~~		<b>*</b> ~ ~~~~	<b>*</b> ••••••	<b>*</b> •••••••	
	0    \$0.0000    \$0.0000    \$0	\$0.0000		\$0.0000	\$0.0000	\$0.0000	_	\$0.0000	\$0.0000	\$0.0000	
Average portion of premium		<b>*</b> ••••••		<b>\$</b> 0,0000	<b>*•</b> • • • • •	<b>*</b> ~ ~~~~		<b>*</b> ~ ~~~~	<b>*</b> ••••••	<b>*</b> •••••••	
		1	_	1	1		_	1	1		
	0 \$0.0000 \$0.0272 <b>\$52,000</b>	\$0.0000		\$0.0000	\$0.0000	\$0.0000		\$0.0000	\$0.0000	\$0.0000	
Enrollee Expenses											Enrollee Expenses
Enrollee expenses for covered											
benefits (deductibles, copays,											benefits (deductibles, copays,
etc.) \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0095 \$18,00	0 \$0.0000 \$0.0095 \$18,000	\$0.0000		\$0.0000	\$0.0000	\$0.0000		\$0.0000	\$0.0000	\$0.0000	etc.)
Enrollee expenses for a second s											
noncovered benefits (e) \$0.00000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.00	0    \$0.0000    \$0.0000    \$0	\$0.0000		\$0.0000	\$0.0000	\$0.0000		\$0.0000	\$0.0000	\$0.0000	noncovered benefits (e)
Total Expenditures \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0000 \$0.0367 \$70,00	0 \$0.0000 \$0.0367 <b>\$70,000</b>	\$0.0000		\$0.0000	\$0.0000	\$0.0000		\$0.0000	\$0.0000	\$0.0000	Total Expenditures
Postmandate Percent Change											Postmandate Percent Change
Percent change insured											Percent change insured
	6 0.0000% 0.0053% 0.0000%	0.0000%		0.0000%	0.0000%	0.0000%		0.0000%	0.0000%	0.0000%	
Percent Change total											
expenditures         0.0000%         0.0000%         0.0000%         0.0000%         0.0000%         0.0000%         0.0000%         0.0000%         0.0001%	<u>6 0.0000% 0.0055% 0.0001%</u>	0.0000%		0.0000%	0.0000%	0.0000%		0.0000%	0.0000%	0.0000%	expenditures

Source: California Health Benefits Review Program, 2020.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Approximately 57.36% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

*Key:* CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

# **PUBLIC HEALTH IMPACTS**

As presented in the *Background on Pelvic Floor Physical Therapy* section, women who have given birth one or more times are at elevated risk for pelvic floor dysfunction (PFD), and risk of PFD continues to increase with age. There is evidence that pelvic floor physical therapy — also referred to as pelvic floor muscle training (PFMT) — is effective in treating urinary incontinence for nonpostpartum women (but inconclusive for postpartum women within 12 months of delivery) and limited evidence of effectiveness in treating pelvic organ prolapse and fecal incontinence for both groups of women. However, evidence of effectiveness is inconclusive or insufficient regarding treatment of urinary incontinence and pelvic pain for postpartum women.

CHBRP projects no measurable statewide public health impact due to existing coverage of PFMT (see *Benefit Coverage, Utilization, and Cost Impacts* section). Almost all enrollees (99.9%) subject to AB 1904 currently have compliant coverage. For the 100 enrollees who gain coverage and newly utilize PFMT services, they could experience reduced urinary incontinence (if nonpostpartum), pelvic organ prolapse, and pelvic pain (if nonpostpartum).

However, CHBRP also concludes that AB 1904 would have no measurable impact on disparities in health outcomes (by gender, race/ethnicity, sexual orientation/gender identity or other determinants) or on societal economic losses described in the *Background on Pelvic Floor Physical Therapy* section.

# LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of AB 1904, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

# Long-Term Utilization and Cost Impacts

## **Utilization and Cost Impacts**

CHBRP estimates no measurable long-term utilization impacts due to existing coverage of pelvic floor muscle training (PFMT) for women.

However, it is possible that enactment of AB 1904 might draw greater attention and interest to PFMT. In turn this could cause some increase in utilization and/or overall cost. CHBRP does not expect this to have a perceptible impact. For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

# **Long-Term Public Health Impacts**

For the same reasons cited in the aforementioned section and the *Public Health* section, CHBRP concludes that AB 1904 would not produce a measurable impact on health outcomes due to existing coverage of medically necessary PFMT.

# APPENDIX A TEXT OF BILL ANALYZED

On January 31, 2020, the California Assembly Committee on Health requested that CHBRP analyze AB 1904.

#### **ASSEMBLY BILL**

NO. 1904

## Introduced by Assembly Member Boerner Horvath

#### January 08, 2020

An act to add Section 1367.623 to the Health and Safety Code, and to add Section 10119.55 to the Insurance Code, relating to health care coverage.

## LEGISLATIVE COUNSEL'S DIGEST

AB 1904, as introduced, Boerner Horvath. Pelvic floor physical therapy coverage. Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan contract or health insurance policy to provide maternity coverage, and prohibits the restriction, reduction, or denial of specified maternity benefits.

This bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2021, to provide coverage for pelvic floor physical therapy after pregnancy. Because a willful violation of the bill's requirements relative to health care service plans would be a crime, the bill would impose a state-mandated local program. The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason. DIGEST KEY

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

#### BILL TEXT

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1367.623 is added to the Health and Safety Code, to read:
1367.623. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2021, shall provide coverage for pelvic floor physical therapy after pregnancy.
(b) "Health care service plan" includes a Medi-Cal managed care plan that contracts with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000) and Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code.

SEC. 2. Section 10119.55 is added to the Insurance Code, to read:

**10119.55**. A health insurance policy issued, amended, or renewed on or after January 1, 2021, shall provide coverage for pelvic floor physical therapy after pregnancy.

**SEC. 3.** No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.
## **APPENDIX B LITERATURE REVIEW METHODS**

This appendix describes methods used in the medical effectiveness literature review conducted for this report. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of PFMT were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete, the Cumulative Index of Nursing and Allied Health Literature, and PsycINFO. Websites maintained by the following organizations that produce and/or index metaanalyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network. The search was limited to abstracts of studies published in English. CHBRP primarily relied on five Cochrane systematic reviews for evidence on the effectiveness of pelvic floor muscle training (PFMT). For more recent studies, the search was limited to studies published since the completion of these Cochrane reviews. Additional studies were identified by reviewing reference lists of relevant papers.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

Of the 459 articles found in the literature review, 50 were reviewed for potential inclusion in this report on AB 1904, and a total of three studies (in addition to the five Cochrane reviews mentioned above) were included in the medical effectiveness review for this report. The other articles were eliminated because they were conducted exclusively in prenatal women, focused on PFMT for prevention of pelvic floor dysfunction, assessed prenatal PFMT on postpartum outcomes, or the PFMT regimens were not overseen by a physiotherapist or physical therapist.

## **Evidence Grading System**

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach*.<sup>24</sup> To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- Clear and convincing evidence;
- *Preponderance of evidence;*

<sup>&</sup>lt;sup>24</sup> Available at: <u>http://chbrp.com/analysis\_methodology/medical\_effectiveness\_analysis.php</u>.

- Limited evidence;
- Inconclusive evidence; and
- Insufficient evidence.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the <u>large majority</u> of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the <u>majority</u> of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

#### Search Terms (\* indicates truncation of word stem)

- 1. Pelvic floor + any of the following
  - o Physical therapy
  - Muscle training
  - Strengthening
  - o Relaxation
  - Biofeedback
  - Electrical stimulation
  - o Internal massage/Theile massage
  - Relaxation exercises
  - Heat application
  - Hyperstimulation analgesia
  - Transcutaneous electrical nerve stimulation (TENS)
  - Neurostimulation
  - Vaginal dilators
- 2. Urinary incontinence
- 3. Overactive bladder
- 4. Pelvic organ prolapse
- 5. Fecal incontinence
- 6. Anal incontinence
- 7. Pelvic floor myofascial pain
- 8. Dyspareunia
- 9. Vaginismus
- 10. Vulvodynia
- 11. Diastatsis recti abdominis
- 12. Women, female
- 13. Pregnancy
- 14. Antenatal
- 15. Postpartum

## APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, Milliman, Inc.<sup>25</sup>

Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impact analyses are available at CHBRP's website.<sup>26</sup>

This appendix describes analysis-specific data sources, estimation methods, caveats, and assumptions used in preparing this cost impact analysis.

#### **Analysis-Specific Caveats and Assumptions**

This subsection discusses the caveats and assumptions relevant specifically to an analysis of AB 1904. Table 1 illustrates that coverage will increase for 0.1% of enrollees with health insurance subject to AB 1904 for CHBRP's analysis of AB 1904 mandating coverage of pelvic floor physical therapy services — also referred to as pelvic floor muscle training (PFMT) — after pregnancy.

- The population subject to the mandated offering includes individuals covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, and publicly funded plans (including CaIPERS and Medi-CaI) subject to the requirements of the Knox-Keene Health Care Service Plan Act.
- Current Procedural Terminology (CPT) codes related to PFMT services were identified based on a review of the claims data sources and discussions with CHBRP's content expert. The following CPT codes were the most frequently utilized codes for PFMT services.

<sup>&</sup>lt;sup>25</sup> CHBRP's authorizing statute, available at <u>http://chbrp.com/CHBRP authorizing statute 2018 FINAL.pdf</u>, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

<sup>&</sup>lt;sup>26</sup> See method documents posted at <u>http://chbrp.com/analysis\_methodology/cost\_impact\_analysis.php;</u> in particular, see 2019 Cost Analyses: Data Sources, Caveats, and Assumptions.

Procedure	CPT Code	
Therapeutic Exercise	97110	
Therapeutic Activity	97530	
Neuromuscular Reeducation	97112	
Manual Therapy	97140	
Gait Training	97116	
Electric Stimulation	97014, 97032	
Traction	97012	
Ultrasound	97035	
Hot or Cold Pack	97010	
Massage Therapy	97124	
Evaluation	97161, 97162	

#### Table 8. CPT Codes Used for the AB 1904 Analysis

 International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) related to PFMT services were identified based on common codes for Pelvic Rehab from Herman & Wallace.<sup>27</sup> The content expert reviewed this list and recommended using all of the codes other than the ICD-10 code for enlarged prostate (N40.1). CHBRP also excluded two codes for lower back pain (M54.5 and M62.830) due to utilization rates much higher than expected for PFMT services. The following ICD-10 codes were used to identify PFMT services.

K58	K58.0	K58.9	K59.0	K59.00	K59.01	K59.02
K59.09	K59.1	K59.4	L90.5	M16	M16.11	M16.12
M16.2	M16.31	M16.32	M16.4	M16.51	M16.52	M25.55
M25.551	M25.552	M25.65	M25.651	M25.652	M35.7	M53.3
M54.3	M54.31	M54.32	M62.0	M62.83	M62.838	M84.35
M84.350	N30.1	N30.10	N30.11	N31	N31.9	N32.81
N34	N39.3	N39.41	N39.42	N39.43	N39.44	N39.45
N39.46	N39.490	N42.81	N81.0	N81.10	N81.2	N81.3
N81.4	N81.5	N81.6	N81.84	N81.89	N94.1	N94.2
N94.4	N94.5	N94.6	N94.810	N94.819	Q79.6	R10.2
R10.30	R14.0	R14.1	R14.3	R15	R15.0	R15.1
R15.2	R15.9	R27.8	R35.0	R35.1	R39.11	R39.12
R39.13	R39.14	R39.15	R39.16	R39.81	R39.89	S33.4

#### Table 9. ICD-10 Codes Used for the AB 1904 Analysis

 The identified CPT and ICD-10 codes were used to extract data from Milliman's 2017 Consolidated Health Cost Guidelines Sources Database (CHSD) and 2017 MarketScan<sup>®</sup> Commercial Claims and Encounters Database (Marketscan), restricting the data pull to California and women only.

<sup>&</sup>lt;sup>27</sup> "ICD-10 Common Codes for Pelvic Rehab Providers." Herman & Wallace Pelvic Rehabilitation Institute. Retrieved February 12, 2020, from <a href="https://hermanwallace.com/images/docs/ICD10-Common-Codes-for-Pelvic-Rehab.pdf">https://hermanwallace.com/images/docs/ICD10-Common-Codes-for-Pelvic-Rehab.pdf</a>.

- Pelvic floor muscle training (PFMT) was identified by claims containing *both* a CPT code for physical therapy *and* an ICD-10 code for pelvic rehab. These data were used to develop baseline cost and utilization information for PFMT after pregnancy. Baseline cost and utilization rates per 1,000 members were calculated and used to estimate the number of visits and average cost per visit. Services for PFMT include both outpatient facility services and professional services.
- Baseline average cost was trended from 2017 to 2021 at an annual rate of 3.3%.
- Baseline utilization was trended from 2017 to 2021 at an annual rate of 0.59%, which is based on Milliman secular trend factors from the Milliman Health Cost Guidelines and the mix of services at outpatient facilities versus professional settings.
- Baseline coverage for PFM services was assumed to be 99.9% of enrollees subject to AB 1904. The basis for this assumption was the carrier survey responses. Members without coverage for PFM were assumed to not utilize PFM services in the baseline scenario.
- Postmandate average cost was assumed to be the same as the baseline average cost for 2021.
- Postmandate utilization was determined by scaling the baseline utilization, both number of PFM utilizers and visits, proportionally to reflect the number of enrollees gaining coverage for PFM services under AB 1904.
- Postmandate coverage for PFMT services was assumed to be 100% of enrollees subject of AB 1904.
- The term "after pregnancy" is assumed to mean any amount of time after pregnancy. CHBRP was not able to identify all women who have ever given birth in the CHSD and Marketscan data. Based on the article by Wu et al. (2014), CHBRP assumed that of the women that had received a PFMT service, 93% of them have given birth. CHBRP used this assumption to convert the data from all women who received a PFMT service to all women who received a PFMT service after pregnancy.
- Responses to the CHBRP survey represent 72% of enrollees in privately funded health insurance market that can be subject to state mandates, 50% of enrollees with Medi-Cal Managed Care Plan coverage, and 71% with CalPERS benefit coverage. Overall, responses to this survey represent 62% of enrollees with health insurance subject to state benefit mandates.

# CHBRP projects a \$73,000 increase in total expenditures as a result of AB 1904 due to survey responses indicating 99.9% coverage of PFMT services.

#### **Determining Public Demand for the Proposed Mandate**

This subsection discusses public demand for the benefits AB 1904 would mandate. Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and
- Compares the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements for description treatment or

service. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CaIPERS currently have the largest number of enrollees. The CaIPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

#### Second Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of AB 1904 would have a substantially different impact on utilization of either the tests, treatments or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second year impacts and determined the second year's impacts of AB 1904 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to potential population changes between the first year postmandate and the second year postmandate.

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The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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